RESEARCH ARTICLE

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A Study on the Impact of a Weekly Versus Three-Weekly Paclitaxel Schedule on Adverse Events in Patients with Solid Malignancies

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ABSTRACT

Cancer is one of the many illnesses that may affect any organ in the body. Cancer cells multiply more than they should. Cancer ranks as the primary or secondary cause of death for those under the age of 70. The most common malignancies worldwide are those of the lung, breast, esophagus, mouth, stomach, liver, and cervix uteri (cervix of the uterus). Paclitaxel was the first known medication to stabilize microtubules and aid in cancer treatment. You can administer Paclitaxel IV for three to twenty-four hours. To determine how each regimen impacts cancer patients' quality of life as indicated by the common terminology criteria for adverse events (CTCAE) scale, our main goal is to evaluate the severity of patients receiving a weekly paclitaxel regimen compared to a three-week regimen. The SVS Medical College and Hospital Mahabubnagar and Mahabubnagar Cancer Hospital served as the sites for this cross-sectional study. The compiled cases include patients with solid malignancies. Every one of these patients would have a clinical PET scan at six months. We have analyzed the collected data using reliable statistical techniques. Our research found that there was a higher risk of cancer development in those between the ages of 40 and 50. Women are more likely than men to have solid cancers. The primary risk factors for cancer are genetics, age, and family history. We divided 120 patients into two groups over six months. We administered weekly paclitaxel to one group at a dosage of 130 mg for ninety minutes, and three weekly chemotherapy programs, each containing 220 mg of paclitaxel spread out over three hours, to the other group. We found that weekly paclitaxel is more effective than three weekly paclitaxels. Patients with lower adverse drug reactions received weekly paclitaxel rather than three times a week. We have concluded that patients with solid malignancies benefit from weekly paclitaxel because it is more efficacious and improves their quality of life. Increasing the dosage causes paclitaxel toxicity over three weeks, which affects each person's quality of life.

Keywords: Tumor, Cancer, Malignancies, Drug Therapy, Chemo regimen, Toxicities.

1. INTRODUCTION

Cancer treatment has evolved significantly over the years, with chemotherapy remaining a cornerstone of management across various solid malignancies.[1] Among the commonly used chemotherapeutic agents, Paclitaxel, a taxane-based cytotoxic drug, plays a pivotal role in treating breast, ovarian, lung, and other solid tumors.[2] Traditionally, Paclitaxel is administered in different dosing schedules, with the most common regimens being the weekly (dose-dense) schedule and the three-weekly (standard) schedule. However, the choice of regimen significantly influences the patient's overall experience, including treatment efficacy, toxicity profile, and quality of life (QoL).[3–7] While the three-weekly regimen delivers a higher dose at longer intervals, the weekly schedule involves lower doses administered more frequently, potentially leading to different patterns of side effects and tolerability. Several studies have explored the comparative efficacy of these schedules, highlighting differences in tumor response, progression-free survival (PFS), and overall survival (OS). However, there remains a gap in understanding the direct impact of these regimens on patient-reported outcomes (PROs), particularly health-

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related quality of life (HRQoL), functional well-being, and chemotherapy-induced toxicities such as neuropathy, fatigue, and hematologic suppression.[8–12]

This study aims to evaluate and compare the impact of weekly versus three-weekly Paclitaxel schedules on the quality of life in patients with solid malignancies. By assessing parameters such as physical functioning, emotional well-being, treatment adherence, and symptom burden, this research seeks to provide valuable insights into patient-centered chemotherapy planning. The findings may help optimize treatment regimens to balance efficacy with tolerability, ultimately improving the overall treatment experience for cancer patients.

2. MATERIALS AND METHODS

2.1. Study designs

- This is a cross-sectional study.

2.2. Source of data

- Patient consent form.
- For demographic details, we used the Data Collection Form.
- Patient questionnaire/interview
- The CTCAE scale specifies common terminology for adverse events.

2.3. Selection criteria

2.3.1. Inclusion criteria

- All patients who received paclitaxel-based chemotherapy at the Department of Medical Oncology
- Patients willing to give their consent for the study
- Patients over 18 years of age

2.3.2. Exclusion criteria

- Paediatric patients
- Pregnant women
- Patients under the age of 18 years

2.4. Method of data collection

- For demographic details we used the Data Collection Form.
- Patient questionnaire/interview
- The CTCAE scale is a commonly used criteria for adverse events.

2.5. Study procedure

This study involves enrolling eligible patients after obtaining their consent, following a cross-sectional approach. We have prepared and utilized a data collection form. This form primarily includes the patient's demographic information and medication chart. The study was conducted at SVS Medical College and Hospital, as well as Mahabubnagar Cancer Hospital. We collected all relevant information from the time of admission until the date of discharge and analyzed the data using appropriate methods.

2.6. Duration of study

The study was conducted from 03-01-2023 to 04-06-2023.

2.7. Place of the study

This study has been conducted at SVS Medical College & Hospital and Mahbubnagar Cancer Hospital.

2.8. Ethics approval and consent to participate

The ethical committee clearance was obtained from the Institutional Ethical Committee of SVS MEDICAL COLLEGE HOSPITAL before initiating the study. Reference number: - IEC/DHR-002/2023/1509.

3. RESULTS AND DISCUSSIONS

3.1. Age-wise distribution

This study involves a total of 120 patients. The findings of this study indicate that solid malignancies tend to occur more frequently in individuals between the ages of 40 and 50, with a total of 50 patients accounting for 41.67% of the sample. Among these patients, 40 were between the ages of 51 and 60, making up 33.33% of the sample. Additionally, there were 20 patients between the ages of 61 and 70, representing 16.67% of the sample, and 10 patients between the ages of 71 and 80, accounting for 8.33% of the sample. Table 1 summarizes these findings.

3.2. Gender-wise distribution

According to the study's findings, it is evident that out of the 120 patients, a larger proportion of females (90 patients, or 75.0%) are more prone for solid malignancies compared to males (30 patients, or 25.0%) (Table 2).

Table 1: Distribution of solid tumors by age

Age	*Number of Patients*	*Percentage*
40-50 years	50	41.67%
51-60 years	40	33.33%
61-70 years	20	16.67%
71-80 years	10	8.33%
Total	120	100%

Table 2: Gender-wise distribution of solid malignancies

Gender	*Number of Patients*	*Percentage*
Male	30	25%
Female	90	75%
Total	120	100%

3.3. Prevalence of solid malignancies in patients

The study's findings revealed that breast cancer was the most common type of cancer, accounting for 63.33% of cases. Lung cancer came in second at 26.67%, followed by bladder cancer at 5.0% and prostate cancer at 5.0%. Table 3 presents these results.

3.4. Treatment schedule of paclitaxel weekly versus three weekly

In this research, we looked at the effects of two distinct paclitaxel treatment plans on a group of 120 patients over six months. The frequency of delivery affects the dose of paclitaxel. For a once-weekly regimen, one group of sixty patients receives a dose of 130 mg over 90 minutes. On the other hand, for a three-weekly regimen, we offer another group of sixty patients a dosage of 220 mg and an extended infusion duration of three hours (Table 4).

3.5. Weekly paclitaxel therapy in solid malignancies patients

According to Table 5, out of the 60 patients who underwent weekly paclitaxel treatment, the majority, 32 patients, had breast cancer, accounting for 53.33% of the total. Additionally, 16 patients had lung cancer, making up 26.67% of the total. The remaining 6 patients each had prostate and bladder cancer, contributing 10.0% of the total.

Table 3: Prevalence of solid malignancies in patients

Solid Malignancies	*No. of patient*	*Percentage*
Breast cancer	76	63.33%
Lung cancer	32	26.67%
Bladder cancer	06	5.%
Prostate cancer	06	5.%
Total	120	100%

Table 4: Treatment schedule of paclitaxel weekly versus 3 weekly

Drug	*No Of Patients*	*Percentage*
Weekly paclitaxel	60	50%
Three weekly paclitaxel	60	50%

Table 5: Weekly paclitaxel therapy in solid malignancies patients

Type of cancer	*No. of patients*	*Percentage*
Breast cancer	32	53.33%
Lung cancer	16	26.67%
Prostate cancer	6	10%
Bladder cancer	6	10%

3.6. Three weekly paclitaxel therapy in solid malignancies patients

Out of the 60 patients, 44 individuals (73.33%) received a breast cancer diagnosis. The remaining 20% (16 patients) received a diagnosis of lung cancer. Table 6 specifies that patients receive paclitaxel three times a week.

3.7. Toxicities observed in weekly and three weekly paclitaxel

Table 7 presents a comparative analysis of adverse drug reactions (ADRs) observed in patients receiving weekly versus three-weekly paclitaxel treatment. The data includes gastrointestinal (GI) issues, hematological toxicity, neurological toxicity, and other ADRs, categorized by occurrence rates (%) and severity based on the Common Terminology Criteria for Adverse Events (CTCAE) scale.

Patients on the weekly paclitaxel regimen exhibited higher incidences of anorexia (10%), nausea (11%), and alopecia (22%), with predominantly Grade 1 toxicity. In contrast, patients on the three-weekly paclitaxel regimen experienced more severe toxicities, including Grade 3 diarrhea (8%), nausea (5%), and peripheral neuropathy (14%), suggesting a higher overall toxicity burden. Hema-

Table 6: Three weekly paclitaxel therapy in solid malignancies patients

Type of cancer	*No. of patient*	*Percentage*
Breast cancer	44	73.33%
Lung cancer	16	26.67%

Table 7: ADRs observed in weekly versus three-weekly pacliltaxel schedules

ADR Type	*Weekly Paclitaxel*	*CTCAE Scale*	*Three Weekly Paclitaxel*	*CTCAE Scale*
Gastrointestinal (GI) Issues				
Diarrhea	05	Grade 1	08	Grade 3
Anorexia	10	Grade 1	02	Grade 2
Nausea	11	Grade 1	05	Grade 3
Vomiting	05	Grade 1		
Hematological Toxicity				
Neutropenia			03	Grade 2
Neurological Toxicity				
Peripheral Neuropathy			14	Grade 3
Others				
Alopecia	22	Grade 1	20	Grade 3
Arthralgia			02	Grade 2
Hypersensitivity Reaction	7	Grade 1	06	Grade 1

tological toxicity (neutropenia, 3%) and arthralgia (2%) were also observed in the three-weekly group.

This table highlights the differences in ADR profiles between the two regimens, indicating that while the weekly schedule may lead to more frequent but milder side effects, the three-weekly schedule is associated with more severe toxicities. These findings emphasize the need for careful patient monitoring and individualized treatment planning to optimize tolerability and therapeutic outcomes. It shows that as the dosage increases, the level of toxicity also increases, negatively impacting the individual's quality of life.

We collected a total of 120 cases during a 6-month study. We collected data based on various studies, considering factors such as age, gender, risk factors, the proportion of solid tumors, and the administration schedule of weekly paclitaxel versus three weekly doses. Our findings reveal that the 40–50 age group is experiencing a significant level of stress. Additionally, our research indicates that this age group is more affected by solid malignancies compared to the 51–60 age group, while the 70–80 age group seems to be the least impacted.[13-17] Another study's findings indicate that women are more likely to develop cancer than men.[18,19] This aligns with our research results. Our study closely aligns with the findings of Kita T, et al. they also identified age and family history as the primary risk factors, followed by smoking, alcohol, and tobacco use, and finally radiation exposure (8.33%).[19] According to the research findings, the prevalence rate of breast cancer is higher than the combined prevalence rates of lung cancer, bladder cancer, and prostate cancer. [20] The results of our study align with prior research that demonstrates the superior progression-free survival (PFS) associated with weekly paclitaxel treatment compared to the three-week regimen. In our study, we compared the effects of two different treatment regimens on a group of 30 patients. One group received weekly paclitaxel at a dose of 130 mg for 90 minutes, while the other group received three-week paclitaxel at a dose of 220 mg for 3 hours.[16]

4. CONCLUSION

This research assesses how the weekly and three-weekly paclitaxel treatment regimens vary in terms of adverse drug reactions (ADRs). The results show that the three-weekly regimen causes more severe toxicities, such as Grade 3 diarrhea, nausea, neutropenia, and peripheral neuropathy, whereas the weekly regimen is linked to a higher incidence of mild-to-moderate ADRs, such as Grade 1 gastrointestinal problems, alopecia, and hypersensitivity reactions. The quality of life of patients is greatly impacted by these severe toxicities, underscoring the need for supportive therapy and cautious dosage modifications to manage these adverse effects. Effective strategies for reducing severe ADRs and improving treatment tolerability include premedication, growth factor support, cryotherapy for neuropathy, and other pharmacologic treatments. A personalized approach that balances toxicity management and effectiveness should be used to choose between the two regimens. Future studies should focus on identifying predictive biomarkers for ADR risks, creating individualized dosing plans, and investigating alternative paclitaxel formulations to improve patient outcomes and reduce complications.

5. LIMITATIONS AND RECOMMENDATIONS

5.1. Limitations

- Due to the 6-month time frame of our study, we were unable to enroll a sample size larger than 120
- We were unable to conduct our study on a large scale due to the limited population size in the center we focused on
- We considered exploring the impact of paclitaxel on non-solid malignancies, but unfortunately, we do not have enough time to conduct the study

5.2. Recommendations

- Future studies can include investigation of the drug's pharmacokinetic and pharmacodynamic properties
- It is possible to study drug interactions and the impact of drugs on different types of cancer
- This study only focuses on a small region in south India. Expanding the study to include more regions would likely yield more accurate and significant results
- All the people in the study share a common origin. The presence of individuals from diverse backgrounds may influence the current findings

6. REFERENCES

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, Bray F. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin*. 2021;71:209-49.
2. Giaccone G, Splinter TA, Debruyne C, Kho GS, Lianes P, van Zandwijk N, et al. Randomized study of paclitaxel-cisplatin versus cisplatin-teniposide in patients with advanced non-small-cell lung cancer. The European Organization for Research and Treatment of Cancer Lung Cancer Cooperative Group. J. Clin. Oncol. 1998;16:2133-41.
3. McGuire WP, Hoskins WJ, Brady MF, Kucera PR, Partridge EE, Look KY, Clarke-Pearson DL, Davidson M. Cyclophos-

phamide and cisplatin compared with paclitaxel and cisplatin in patients with stage III and stage IV ovarian cancer. N. Engl. J. Med. 1996;334:1-6.

4. Holmes FA, Walters RS, Theriault RL, Forman AD, Newton LK, Raber MN, Buzdar AU, Frye DK, Hortobagyi GN. Phase II trial of taxol, an active drug in the treatment of metastatic breast cancer. J. Natl. Cancer. Inst. 1991;83:1797-805.
5. Ball HG, Blessing JA, Lentz SS, Mutch DG. A phase II trial of paclitaxel in patients with advanced or recurrent adenocarcinoma of the endometrium: a Gynecologic Oncology Group study. Gynecol. Oncol. 1996;62:278-81.
6. Papadimitriou CA, Sarris K, Moulopoulos LA, Fountzilas G, Anagnostopoulos A, Voulgaris Z, et al. Phase II trial of paclitaxel and cisplatin in metastatic and recurrent carcinoma of the uterine cervix. J. Clin. Oncol. 1999;17:761-6.
7. Katsumata N, Yasuda M, Isonishi S, Takahashi F, Michimae H, Kimura E, Aoki D, Jobo T, Kodama S, Terauchi F, Sugiyama T, Ochiai K, and Japanese Gynecologic Oncology Group. Long-term results of dose-dense paclitaxel and carboplatin versus conventional paclitaxel and carboplatin for treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (JGOG 3016): a randomised, controlled, open-label trial. Lancet. Oncol. 2013;14:1020-6.
8. Tamura K, Inoue K, Masuda N, et al. Randomized phase II study of nab-paclitaxel as first-line chemotherapy in patients with her2-negative metastatic breast cancer. Cancer Sci. 2017;108(5):987-994.
9. Sakakibara T, Inoue A, Sugawara S, Maemondo M, Ishida T, Usui K, et al. Randomized phase II trial of weekly paclitaxel combined with carboplatin versus standard paclitaxel combined with carboplatin for elderly patients with advanced non-small-cell lung cancer. Ann. Oncol. 2010;21:795-9.
10. Lakka NS, Kuppan C, Vadagam N, Ravinathan P, Chepuri K, Chinnakadoori SR. Molecular docking, in-vitro anticancer evaluation and ADME profiling of 7-Oxo Midostaurin. Journal of molecular structure. 2023;1293:136159-9
11. Belani CP, Ramalingam S, Perry MC, LaRocca RV, Rinaldi D, Gable PS, et al. Randomized, phase III study of weekly paclitaxel in combination with carboplatin versus standard every-3-weeks administration of carboplatin and paclitaxel for patients with previously untreated advanced non-small-cell lung cancer. J. Clin. Oncol. 2008;26:468-73.
12. Ettinger DS, Wood DE, Aggarwal C, et al. NCCN Guidelines Insights: Non-Small Cell Lung Cancer, Version 1.2020. J Natl Compr Canc Netw. 2019;17(12):1464-1472.
13. Gradishar WJ, Anderson BO, Abraham J, Aft R, Agnese D, Allison KH, et al. Breast Cancer, Version 3.2020, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw. 2020;18:452-78.
14. Nielson CM, Bylsma LC, Fryzek JP, Saad HA, Crawford J. Relative dose intensity of chemotherapy and survival in patients with advanced stage solid tumor cancer: a systematic review and meta-analysis. Oncologist. 2021;26(9):e1609-e1618
15. Daly MB, Pilarski R, Yurgelun MB, Berry MP, Buys SS, Dickson P, et al. NCCN Guidelines Insights: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic, Version 1.2020. J Natl Compr Canc Netw. 2020;18:380-91.
16. Qi M, Li JF, Xie YT, Lu AP, Lin BY, Ouyang T. Weekly paclitaxel improved pathologic response of primary chemotherapy compared with standard 3 weeks schedule in primary breast cancer. Breast Cancer Res Treat. 2010;123:197-202.
17. Clamp AR, James EC, McNeish IA, Dean A, Kim JW, O'Donnell DM, et al. Weekly dose-dense chemotherapy in first-line epithelial ovarian, fallopian tube, or primary peritoneal carcinoma treatment (ICON8): primary progression free survival analysis results from a GCIG phase 3 randomised controlled trial. Lancet. 2019;394:2084-95.
18. Mirtsching B, Cosgriff T, Harker G, et al. A phase II study of weekly nanoparticle albumin-bound paclitaxel with or without trastuzumab in metastatic breast cancer. Clin Breast Cancer. 2011;11(2):121-128.
19. Kita T, Kikuchi Y, Takano M, Suzuki M, Oowada M, Konno R, et al. The effect of single weekly paclitaxel in heavily pretreated patients with recurrent or persistent advanced ovarian cancer. Gynecology Oncol. 2004;92(3):813-8.
20. Baird RD, Tan DS, Kaye SB. Weekly paclitaxel in the treatment of recurrent ovarian cancer. Nat Rev Clin Oncol. 2010;7(10):575-82.

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